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PRELIMINARY STATEMENT

The United States of America (“United States” or “Government”) respectfully submits this memorandum of points and authorities in opposition to the Motion to Dismiss the United States’ Complaint in Intervention and to Strike Portions Thereof (“Motion”) filed by Defendant Mallinckrodt ARD LLC (formerly Mallinckrodt ARD, Inc., formerly Questcor Pharmaceuticals, Inc.) (collectively “Mallinckrodt,” the “Defendant”, or the “Company”). Mallinckrodt contends that the United States’ Complaint in Intervention (“Complaint”) fails to state a plausible scheme by which Mallinckrodt knowingly violated the False Claims Act (“FCA”) and asks the Court to strike a paragraph and footnote from the Complaint. As discussed in detail below, Mallinckrodt’s arguments ignore the detailed and specific factual allegations in the Complaint and the governing law, and misconstrue the applicability and content of the materials attached to the Motion. The Motion should be denied.

BACKGROUND

The United States pleads a plethora of facts alleging that Mallinckrodt engaged in a scheme to pay illegal copay subsidies for Acthar in violation of the Anti-Kickback Statute (“AKS”) and the FCA. The Complaint alleges specifically that Mallinckrodt engaged in the alleged fraud after exponentially increasing Acthar’s price and reaping profits for uses that the company acknowledged it could not profit from absent the fraudulent scheme. The Complaint explains that Mallinckrodt believed paying copay subsidies for Acthar was necessary to induce significant sales. The Complaint describes how Mallinckrodt designed and used three “exacerbation” funds at Chronic Disease Fund (now d/b/a Good Days) (“CDF”) to pay the copays of Acthar—but no other drugs—so it could market Acthar as “free” to patients and physicians despite the ever-increasing price. Taken together, these facts lead to only one

conclusion: the Complaint alleges plausible and particularized violations of the AKS and FCA similar to others that courts have held to be actionable. *See United States ex rel. Vitale v. MiMedx Grp., Inc.*, 381 F. Supp. 3d 647, 659 (D.S.C. 2019).

Rather than articulating a cognizable argument that the Complaint fails to satisfy the applicable pleading standards, Mallinckrodt instead bases its motion on an asserted a factual disagreement, which cannot be a basis for dismissal at the pleadings stage. But even the basis for Mallinckrodt's factual dispute is belied by the Complaint and the publicly available materials it invokes. The Company also asks the Court to strike under Rule 12(f) a portion of the Complaint demonstrating the United States' regular enforcement of AKS violations for illegal copay subsidies. This argument is meritless, as such materials are not scandalous or impertinent or even offered for the purpose Mallinckrodt appears to take issue with. Mallinckrodt's motion should be denied.

ARGUMENT

I. THE WELL-PLED COMPLAINT ALLEGES THAT MALLINCKRODT VIOLATED THE FALSE CLAIMS ACT BY PAYING ILLEGAL COPAY SUBSIDIES FOR ACTHAR

A. LEGAL STANDARD

Under Federal Rule of Civil Procedure 8(a)(2), “[a] pleading that states a claim for relief must contain . . . a short and plain statement of the claim showing that the pleader is entitled to relief[.]” *Id.*; *see also Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 573 (2007). Therefore, “[t]o survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face.” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quotation omitted). “A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the

misconduct alleged.” *Id.* (citation omitted); *see United States ex rel. Bookwalter v. UPMC*, No. 18-1693, 2019 WL 4437732, *3 (3d. Cir. Sept. 17, 2019) (“[W]e ask only if we have enough facts to raise a reasonable expectation that discovery will reveal evidence of each element.”) (quotation omitted) (reversing dismissal of FCA relator’s allegations). In evaluating motions to dismiss under Federal Rule 12(b)(6), courts “accept all factual allegations as true, construe the complaint in the light most favorable to the plaintiff, and determine whether, under any reasonable reading . . . the plaintiff may be entitled to relief.” *Phillips v. Cty. of Allegheny*, 515 F.3d 224, 233 (3d Cir. 2008) (quotation omitted); *see Connelly v. Lane Const. Corp.*, 809 F.3d 780, 786 (3d Cir. 2016) (rejecting that the “plausibility standard” is akin to a “probability requirement”); *McDermott v. Clondalkin Grp., Inc.*, 649 F. App’x 263, 269 n. 3 (3d Cir. 2016) (rejecting defendant’s factual contentions and reversing dismissal).

Federal Rule of Civil Procedure Rule 9(b) provides that “[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake,” *id.*, which is met in the FCA context by “particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted.” *Foglia v. Renal Ventures Mgmt., LLC*, 754 F.3d 153, 156-57 (3d Cir. 2014). “Malice, intent, knowledge and other conditions of a person’s mind may be alleged generally.” Fed. R. Civ. P. 9(b); *see Smith v. Carolina Med. Ctr.*, 274 F. Supp. 3d 300, 321 (E.D. Pa. 2017) (FCA knowledge “may be alleged generally under Rule 9(b).”).

1) The False Claims Act

The False Claims Act is “the Government’s primary litigative tool” for combatting fraud. S. Rep. No. 99-345, at 2 (1986), *as reprinted in* 1986 U.S.C.C.A.N. 5266, 5266. The FCA imposes liability when a person “knowingly presents, or causes to be presented, a false or

fraudulent claim for payment or approval.” 31 U.S.C. § 3729(a)(1)(A). A plaintiff properly alleges a violation of 31 U.S.C. § 3729(a)(1)(A) by alleging that (1) the defendant presented or caused to be presented a claim for payment; (2) the claim was false or fraudulent; and (3) the defendant knew the claim was false or fraudulent. *Id.*; see *United States ex rel. Wilkins v. United Health Grp., Inc.*, 659 F.3d 295, 305 (3d Cir. 2011). The terms “knowing” and “knowingly” under the FCA “(A) mean that a person, with respect to information -- (i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information; and (B) require no proof of specific intent to defraud.” 31 U.S.C. § 3729(b)(1). The FCA also imposes liability when a person “knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim,” 31 U.S.C. § 3729(a)(1)(B), and a plaintiff properly alleges a violation of Section 3729(a)(1)(B) by alleging that (1) the defendant made or used, or caused someone else to make or use, false records or statements; (2) the defendant knew the records were false or fraudulent; and (3) the records were material to false claims submitted to the United States. *Id.* The FCA defines “material” to mean “having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property.” 31 U.S.C. § 3729(b)(4).

2) The Anti-Kickback Statute

The AKS, 42 U.S.C. § 1320a-7b(b)(2)(B), prohibits “knowingly and willfully offer[ing] or pay[ing] any remuneration . . . directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person . . . to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program.” *Id.* The AKS specifies that

remuneration includes any “kickback, bribe, or rebate” paid “in cash or in kind,” *id.* and that “actual knowledge [of the AKS] or specific intent” is not required. *Id.* at § 1320a-7b(h). The Government must show that just “one purpose” of the remuneration was to induce Medicare purchases or referrals. *United States v. Greber*, 760 F.2d 68, 69 (3d Cir. 1985).

Allegations that a defendant knowingly and willfully paid or waived Medicare copays, including indirect payments to pay Medicare copays disguised as charitable contributions to a foundation, properly state an AKS violation. *See e.g., Vitale* 381 F. Supp. 3d at 659 (“Relator sufficiently alleges an AKS violation because he claims Defendant knowingly and willfully paid a remuneration, here Medicare coinsurance and copays, indirectly via its correlated charitable contribution funding of [Patient Access Network Foundation], to induce patients on Medicare to purchase Defendant's Products”); *see also, e.g. United States ex rel. Lutz v. Berkeley Heartlab, Inc.*, 225 F. Supp. 3d 487, 499 n.3 (D.S.C. 2016) (finding waiver of patients' copay with intent to induce states an AKS claim). And as Mallinckrodt acknowledges, claims for payment made pursuant to illegal kickbacks are false under the FCA. Def's Mot. at 13.

B. THE COMPLAINT'S DETAILED ALLEGATIONS SATISFY EACH ELEMENT OF THE AKS AND FCA

The Complaint pleads detailed conduct satisfying each element of the AKS and the FCA. Mallinckrodt's motion to dismiss should be denied.

1) The Complaint Properly Pleads That Mallinckrodt Violated the AKS

The Complaint properly alleges that Mallinckrodt violated the AKS, 42 U.S.C. § 1320a-7b(b)(2)(B), because it alleges that Mallinckrodt: 1) provided remuneration, 2) with an intent to induce Medicare-reimbursed purchases of Acthar, and 3) did so knowingly and willfully. First, the Complaint alleges that Mallinckrodt provided remuneration, namely financial subsidies to pay Acthar Medicare copays. The Complaint alleges a scheme by Mallinckrodt to pay thousands

of Acthar Medicare copays by making at least fifty payments to CDF totaling over \$23 million, Compl. ¶ 155, knowing that CDF would use this money to pay the Medicare copays for Acthar (but no other drug) because Mallinckrodt designed the funds to ensure this. *See, e.g., id.* ¶¶ 2, 5-6, 73-133, 137-155; 205-216. The Complaint further alleges the dates and amounts of 121 specific Acthar copay subsidies provided by Mallinckrodt via CDF as examples of this illegal scheme. Compl. Ex. 3-4; *see id.* ¶¶ 211-214.

Second, the Complaint alleges that Mallinckrodt provided the remuneration with an intent to induce Medicare-reimbursed purchases of Acthar.¹ *See, e.g.,* Compl. ¶¶ 2, 5, 45-46, 105, 137, 145, 161, 205, 214, 217. Indeed, the purpose of Mallinckrodt's scheme was to ensure patients would fill (and Medicare would pay for) prescriptions for Acthar at over \$23,000 per vial (and later over \$32,000 per vial), knowing that the drug's price otherwise posed a barrier to Acthar sales. *Id.*; *see also id.* ¶¶ 4, 71, 74-75, 79, 80-83. Mallinckrodt incorporated the copay scheme into its commercial operations, for example, by instructing its hub, ASAP, to "proactively offer[] copay assistance to all patients" with a copay above \$150 to make sure the company was not "losing some referrals where the patient does not receive an automatic offering of copay assistance." *Id.* ¶ 131; *see also id.* ¶¶ 5, 6, 78, 79. Mallinckrodt also excluded patients with Medicare coverage from its free drug program in favor of routing them to receive a copay subsidy that would result in Medicare covering the cost of the drug. *Id.* ¶¶ 134-136.

Meanwhile, Mallinckrodt marketed the drug as free to doctors and patients on account of these copay subsidies, as part of an aggressive sales push to overcome objections about the

¹ Medicare Part D is a "Federal healthcare program" for purposes of the AKS and a Medicare Part D Acthar prescription constitutes a "good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program." *See* Compl. ¶ 41; 42 U.S.C. §§ 1320a-7b(b)(2), (f); *see also* Compl. ¶¶ 19-30; 186-193.

drug's cost and induce Medicare purchases at the high price. *See e.g., id.* ¶¶ 2, 4, 5, 137-145.² Mallinckrodt instructed sales representatives: "DO NOT APOLOGIZE FOR THE PRICE" but instead explain that "we offer an excellent co-pay coverage program" and "the process is fast." *Id.* ¶ 139. Mallinckrodt knew that its salesforce relied on copay subsidies as a "selling tool" because it instructed them to do so. *Id.* ¶ 143. Management deemed this tactic essential because its "reps are out there selling the most expensive drug on the planet[.]" *Id.* ¶ 144. Mallinckrodt also cited more copay subsidies as a "Way[] to Drive Acthar Prescribing," and even "the most motivating factor" to prescribe Acthar. *Id.* ¶ 79, *see id.* ¶¶ 142, 157. The Complaint thus alleges that "one purpose" of the scheme was to induce Medicare to buy Acthar. *Greber*, 760 F.2d at 69.

Third, the Complaint alleges that Mallinckrodt paid this remuneration knowingly and willfully. The Complaint not only alleges Mallinckrodt's scienter generally which is all that is required, *see id.* ¶¶ 2, 45, 161, 217, but provides seven pages and 24 paragraphs of detailed allegations in a separate section dedicated to Mallinckrodt's knowing and willful conduct.

Compl. ¶¶ 162-184. They include that:

- Mallinckrodt had knowledge and understanding of: (1) the AKS and its prohibition on paying remuneration with an intent to induce purchases or referrals; and (2) the FCA and its prohibition on submitting or causing to be submitted false claims to Medicare, including claims tainted by kickbacks; *id.* ¶ 162
- Mallinckrodt's corporate training and policies reflected this understanding of the AKS and FCA, *id.* ¶¶ 163-64, and further recognized that "referrals to financial assistance programs or patient assistance programs" to induce the use or purchase of Acthar would violate the AKS; *id.* ¶¶ 165-66;
- Mallinckrodt employees who designed the copay scheme understood the law and these trainings and acknowledged that the company could not legally pay Medicare copays of its own products, *id.* ¶¶ 167-68, but demanded Acthar-specific funds at CDF to accomplish the very same result; *see, e.g., id.* ¶ 169;

² Mallinckrodt itself believed the cost posed a barrier in part due to cheaper competition and what the company described as a lack of efficacy data justifying the cost. Compl. ¶¶ 4, 81-83.

- Mallinckrodt was aware of warnings by the United States Department of Health and Human Services, Office of the Inspector General (“HHS-OIG”) dating back to 2005 on the AKS risks posed by a drug company paying Medicare copays indirectly through a foundation or seeking to use a foundation as a conduit to do so; *id.* ¶¶ 170-179; and
- Mallinckrodt created an arrangement that did not avoid the risks that HHS-OIG had warned against, including by directly or indirectly influencing CDF, *id.* ¶ 181, to create Acthar-specific symptom funds at the exclusion of other drugs, *id.* ¶ 182, and funding Acthar subsidies through them based on detailed financial data, *id.* ¶ 183, to keep Mallinckrodt’s copay conduit functioning smoothly so it could reliably market Acthar as “free” despite its sky-high cost. *See id.* ¶ 180, 184.

The Complaint also alleges efforts by Mallinckrodt to conceal the true nature of its conduct with CDF, which is also demonstrative of a knowing and willful intent. *See, e.g., United States v. Starks*, 157 F.3d 833, 839 n.8 (11th Cir. 1998) (recognizing that “furtive” conduct supports an inference that defendants knew they were acting unlawfully). For example, the Complaint alleges that Mallinckrodt signed contracts with CDF that concealed Mallinckrodt’s role in creating the funds, Compl. ¶¶ 95-97, and that Mallinckrodt engaged in a deliberate scheme to “exclude” other drugs through “exacerbation” funds while using the funds to subsidize long-term “pulse maintenance” Acthar prescriptions anyway. *See id.* ¶¶ 101, 102, 103, 112, 115. The complaint also alleges that Mallinckrodt ignored red flags, such as CDF needing to consult with its own attorneys about the arrangement and CDF finally closing the funds altogether. *Id.* ¶¶ 121-127, 154. The Complaint properly pleads each element of the AKS and thus properly states a claim that Mallinckrodt violated the AKS.

2) The Complaint Properly Pleads That Mallinckrodt Violated the FCA

The Complaint also alleges that, on account of these AKS violations, Mallinckrodt: knowingly presented or caused to be presented false claims to Medicare for reimbursement of Acthar purchases and knowingly made, used, or caused someone else to make or use, false

records or statements material to those claims. *See, e.g.* Compl. ¶¶ 223-230. The Complaint thus properly pleads a violation of the FCA.

The Complaint alleges a scheme by Mallinckrodt to pay illegal Acthar copay subsidies in violation of the AKS resulting in Medicare's payment of over 2,600 of Acthar prescriptions tainted by these illegal kickbacks. *Id.* ¶ 205; *see also id.* ¶¶ 2, 5, 7, 44-46, 75-76, 128-133, 136, 185-230. As Mallinckrodt correctly acknowledges, "[c]laims for payment made pursuant to illegal kickbacks are false under the False Claims Act." Def's Mot. at 13 (quoting *United States ex rel. Greenfield v. Medco Health Sols., Inc.*, 880 F.3d 89, 95 (3d Cir. 2018)); *see* 42 U.S.C. § 1320a-7b(g) ("a claim that includes items or services resulting from [an AKS violation] constitutes a false or fraudulent claim for purposes of [the FCA]"). Therefore, because the Complaint properly pleads an AKS violation, it establishes that these claims are false or fraudulent under the FCA. *Id.* Moreover, the Complaint goes well beyond the pleading requirement to allege a strong inference that claims were actually submitted, *Foglia*, 754 F.3d at 156-57, and pleads over 120 specific examples of false Medicare claims for which Mallinckrodt provided illegal copay subsidies, as documented in false Prescription Drug Event (PDE) data. Compl. ¶¶ 186-193, 206-222; Ex. 1-4.³

The Complaint also alleges that Mallinckrodt knew the claims and records were false and thus acted "knowingly" for purposes of the FCA. These general allegations alone are sufficient. *Id.* ¶¶ 46; 218, 224, 225, 228, 229; Federal Rule 9(b); *Smith*, 274 F. Supp. 3d at 321. But, as

³ Exceeding the pleading requirement, the Complaint sets forth numerous representations in each false claim, including that each is an Acthar prescription for which Mallinckrodt paid a copay subsidy through CDF, Compl. ¶¶ 207, 211, 212; the amount and date of the illegal subsidy Mallinckrodt paid, *id.* ¶¶ 214, 215; the date of the Medicare claim and the amount of Acthar dispensed, *id.* ¶ 208; and the Medicare cost of each prescription. *Id.* ¶ 209. *See United States ex rel. Gohil v. Sanofi-Aventis U.S. Inc.*, 96 F. Supp. 3d 504, 517 (E.D. Pa. 2015) (Plaintiffs need not "plead the details of particular false claims" to survive a motion to dismiss)

discussed above, the Complaint alleges numerous details corroborating them. *See supra* at 8-9; *see, e.g.*, Compl. ¶¶ 45-46, 95-97, 101-103, 112, 115, 161-184, 217.

Because the Complaint properly pleads all the elements of these FCA violations predicated on Mallinckrodt's underlying AKS violations, the Complaint adequately states a claim that Mallinckrodt violated 31 U.S.C. § 3729(a)(1)(A) and (B).

II. MALLINCKRODT'S ARGUMENT THAT THE COMPLAINT FAILS TO STATE A CLAIM LACKS MERIT

Mallinckrodt argues that, despite detailed allegations satisfying every element of each statute, the Complaint nevertheless fails to state a claim under the AKS and FCA. Mallinckrodt first argues that the Complaint's allegations cannot constitute an AKS because of certain HHS-OIG guidance it attaches to its motion. Def's Mot. at 14-19. Mallinckrodt next argues that those same materials bear on the question of whether the Complaint plausibly alleges that Mallinckrodt acted with the requisite scienter. Def's Mot. at 19-22. The premise of both arguments is a factual assertion by Mallinckrodt that the Company's conduct "was consistent with OIG guidance during the relevant time frame[.]" Def's Mot. at 14; *see also* Def's Mot. at 10, n. 11. This assertion is not a ground to dismiss the well-pled Complaint and, in any event, is belied by the allegations. Moreover, in making both arguments, Mallinckrodt misconstrues the applicability and content of the very materials it relies on which, in truth, undermine Mallinckrodt's arguments.

A. MALLINCKRODT MISCONSTRUES THE HHS-OIG GUIDANCE IT INVOKES

Mallinckrodt argues that the conduct alleged cannot amount to an AKS violation as a legal matter because of the existence of guidance or advisory opinions issued by HHS-OIG (none of which were issued to Mallinckrodt). Def's Mot. at 14-18. Mallinckrodt does not cite a single

case for this proposition and the argument must fail. First, agency guidance does not alter the elements of the AKS, and the Complaint's detailed allegations satisfy each element of the statute. Second, Mallinckrodt fundamentally misconstrues the materials on which it relies; in fact these materials confirm that HHS-OIG has consistently warned drug companies *away* from the very conduct alleged here, rather than endorsing it as Mallinckrodt suggests. Third, Mallinckrodt's argument is based on a factual assertion that the company conformed to the guidance, which is belied by the Complaint and not a ground to dismiss well-pled claims in any event.

1) The Test for Whether Mallinckrodt Violated the AKS is the AKS Itself

A drug company knowingly and willfully paying a Medicare patient to fill a Medicare-reimbursed prescription of the company's own product, either directly or indirectly and with an intent to induce that purchase, violates the AKS. 42 U.S.C. § 1320a-7b(b)(2); *see e.g., Vitale* 381 F. Supp. 3d at 659. That HHS-OIG has issued an advisory opinion to a self-certified non-profit entity seeking to provide copay assistance to federal patients, in which the agency agrees to refrain from administrative enforcement action against the non-profit so long as it follows certain safeguards, does not alter the elements of the AKS needed to establish a violation by the drug company.⁴ Nor does other agency guidance. The ultimate analysis with respect to whether Mallinckrodt violated the AKS is comparing Mallinckrodt's alleged conduct to the statute's elements. The allegations in the Complaint amply satisfy them, as discussed above.

⁴ Indeed, every advisory opinion Mallinckrodt cites states that it applies only to the requestor and, even there, only as to the fact pattern and safeguards certified therein. Decl. of John Joseph Exhibit ("Def's Ex.") A at 10 ("This advisory opinion has no application to, and cannot be relied upon by, any other individual or entity" and "may not be introduced into evidence in any matter involving an entity or individual that is not the requestor of this opinion" and has "no applicability to other arrangements, even those which appear similar in nature or scope."); *see* Def's Ex. D at 7-8; E at 10; F at 9-10; G at 14; H at 10; I at 14; J at 9; K at 10-11.

Moreover, HHS-OIG materials issued to parties other than Mallinckrodt do not create new conditions—the non-compliance with which must be pled or shown—to establish an AKS violation against Mallinckrodt. At least one court has already concluded as much, recently denying a motion to dismiss AKS allegations against a medical device manufacturer arising from financial contributions to Patient Access Network Foundation (“PAN”)—one of the foundations whose advisory opinion Mallinckrodt attaches to its motion to dismiss. The court did so by applying the AKS elements to the manufacturer’s conduct without regard to PAN’s Advisory Opinion. *Vitale* 381 F. Supp. 3d at 659 (D.S.C. 2019); *see* Def’s Ex. I.⁵

A recent Third Circuit decision further confirms that such pleading is not required. *Bookwalter*, No. 18-1693, 2019 WL 4437732 at *15-16. The *Bookwalter* court reversed a dismissal of FCA claims premised on Stark Act violations, which prohibits physician self-referral arrangements. The court rejected defendant’s arguments that, to state a plausible claim, relators must plead non-compliance with statutory or regulatory exceptions to the Stark Act. *Id.* Here, Mallinckrodt relies on general guidance or advisory opinions issued to others—none of which is even analogous to a regulatory exception—to make essentially the same argument. This Court should follow the Third Circuit’s holding and reject defendant’s argument.

2) Mallinckrodt Misconstrues the HHS-OIG Materials It Relies On

Mallinckrodt also mischaracterizes the public materials it attaches to its motion, suggesting they amount to a blanket endorsement by HHS-OIG of drug companies subsidizing the Medicare copays of their own products and that—only later—HHS-OIG expressed concern

⁵ Although Mallinckrodt provided a redacted version of this Advisory Opinion, PAN’s website publicizes that it is the recipient of Advisory Opinion 07-18. (<https://panfoundation.org/files/OIGAdvisoryOpinionNo07-18December2007.pdf>).

about these schemes. Nothing could be further from the truth. Far from a blanket approval, since 2005 HHS-OIG has consistently warned drug companies that subsidizing Medicare copays poses AKS risks, animated by a concern that “the use of [copay] subsidies” could “eliminat[e] a market safeguard against inflated [drug] prices” paid by Medicare. *Special Advisory Bulletin: Patient Assistance Programs for Medicare Part D Enrollees*, 70 Fed. Reg. 70,623, 70,626 (Nov. 22, 2005) (“2005 SAB”); see Compl. ¶¶ 173-74.

Indeed, HHS-OIG repeatedly emphasized key safeguards it viewed as necessary to minimize the risk of an AKS violation in such indirect drug company payments to beneficiaries, even when made through purportedly charitable foundations. 2005 SAB at 70,626; see Compl. ¶¶ 170-179. For example, HHS-OIG cautioned against any “direct or indirect influence or control” by the drug company over the foundation. 2005 SAB at 70,626 (“[n]either the pharmaceutical manufacturer nor any affiliate of the manufacturer . . . exerts any direct or indirect influence or control over the charity or the subsidy program”); Compl. ¶ 177. HHS-OIG voiced particular concern where drug companies “seek improperly to maximize . . . profits by creating sham ‘independent’ charities” or “by colluding with independent charity programs to ensure that the manufacturer’s contributions only or primarily benefit patients using its products[.]” 2005 SAB at 70,626; Compl. ¶ 174.

HHS-OIG opined that influencing a foundation to create an artificially narrow fund defined in reference to a disease’s symptoms to cover just the donor’s product created risk:

[W]e are concerned that, in some cases, charities may artificially define their disease categories so narrowly that the earmarking effectively results in the subsidization of one (or a very few) of donor's particular products. **For example, we would be concerned if disease categories were defined by reference to specific symptoms, severity of symptoms, or the method of administration of drugs, rather than by diagnoses or broadly recognized illnesses or diseases.** This type of arrangement would present an elevated risk of fraud and abuse because of the increased likelihood that the PAP would function as an improper

conduit for manufacturers to provide funds to patients using their specific drugs. **To avoid this risk, pharmaceutical manufacturers should not influence, directly or indirectly, the identification of disease or illness categories, and pharmaceutical manufacturers should limit their earmarked donations to PAPs that define categories in accordance with widely recognized clinical standards and in a manner that covers a broad spectrum of available products.**

2005 SAB at 70,627 (emphasis added); Compl. ¶ 176. HHS-OIG also cautioned drug companies about seeking data to correlate their donations to subsidies of their own products. 2005 SAB at 70,626; Compl. ¶ 177. And, overall, HHS-OIG warned that such foundations “must not function as a conduit for payments by the pharmaceutical manufacturer to patients.” 2005 SAB at 70,627; Compl. ¶ 175. CDF’s Advisory Opinion includes substantively the same safeguards. Compl. ¶ 178; Def’s Ex. A at 5, 8.⁶ So does every other advisory opinion Mallinckrodt cites issued after the 2005 SAB and opining on Medicare Part D prescription drug copay subsidies. *See* Def’s Ex. E at 4,8; F at 4,7; G at 5,11; H at 3-4, 7-8; I at 5-6,12.

Mallinckrodt relies heavily on HHS-OIG’s statement in a footnote of the 2005 SAB, and similar footnote in CDF’s 2006 Advisory Opinion—that in certain “rare circumstances” a fund with just one drug “standing alone” is not “determinative of an [AKS] violation.” Def’s Mot. at 6, 14, 15, 18. But even Mallinckrodt acknowledges that AKS violations in such “rare circumstances” are not only possible, but triggered by the surrounding facts and intent of the

⁶ Indeed, the only arrangement approved by CDF’s Advisory Opinion is one where: 1) “no donor . . . exerts any direct or indirect influence or control” and “no donor . . . directly or indirectly influences the identification or delineation of Funded Diseases”; 2) “Funded Diseases are not . . . defined by reference to specific symptoms or severity of symptoms” but rather “in accordance with widely recognized clinical standards and in a manner that covers a broad spectrum of available products”; and 3) “[CDF]’s reports to donors do not contain any information that would enable a donor to correlate the amount or frequency of its donations with the number or medical condition of patients that use its products or services, or the volume of those products or services.” Def’s Ex. A at 5, 8.

parties: “a determination [of an AKS violation in these circumstances]” is made “on a case-by-case basis after examining all of the applicable facts and circumstances, including the intent of the parties.” 2005 SAB at 70627 n.19; Def’s Mot. at 18.

Mallinckrodt also suggests that HHS-OIG guidance issued in 2014 was a change in position with regard to conduct alleged in the Complaint. *See* Def’s. Mot. 17-18; *see also* Def’s Mot. at 20-22. This is false. The 2014 guidance called for certain enhanced safeguards and reaffirmed warnings contained in prior guidance, which Mallinckrodt already ignored. The 2014 guidance itself is explicit about this fact.⁷

3) The Complaint Alleges a Litany of Conduct That Falls Outside the Safeguards in the HHS-OIG Materials from the Relevant Time Period

Although not a requirement to establish an AKS violation, the Complaint includes detailed facts showing a scheme whereby Mallinckrodt failed to adopt the safeguards identified in the very guidance it cites in its Motion. Put simply, guidance that was not issued to Mallinckrodt, which the Company knew about and then ignored, cannot now immunize Mallinckrodt from liability. The Complaint details that Mallinckrodt’s arrangement here did not fall within the HHS-OIG guidance in place at the time, and ignored the guidance’s warnings, in at least the following ways:

⁷ For example, the 2014 guidance states:

[W]e discuss and expand on some of the safeguards that we originally set forth in the 2005 SAB . . . [and] [o]ne of the points we made in the [2005 SAB] was that pharmaceutical manufacturers and their affiliates should not exert any direct or indirect influence or control over the charity or its assistance program. We also stated that donors should not influence the identification of disease funds and that we would be concerned if disease funds were defined by reference to specific symptoms, severity of symptoms, or the method of administration of drugs.

Supplemental Special Advisory Bulletin: Independent Charity Patient Assistance Programs, 79 Fed. Reg. 31,120, 31,121 (May 30, 2014) (“2014 SAB”). *See id.* at 31,121, n.8

Influence. The Complaint alleges that Mallinckrodt influenced CDF's creation of the MS, Lupus, and RA "exacerbation" funds by insisting that CDF create each new fund for Mallinckrodt to support Acthar marketing efforts. Compl. ¶ 181. For example, CDF did not operate or create any of the funds at issue in this case on its own volition or independent charitable determination. Rather, Mallinckrodt influenced CDF to open funds that *Mallinckrodt* wanted. *See, e.g.*, Compl. ¶ 88 (alleging Mallinckrodt influenced CDF to open a separate fund—rather than donating to CDF's existing MS fund—to "prevent chronic MS needs from tapping the funds"); Compl. ¶ 110 (Reimbursement Manager to CDF: "*we* are moving into . . . lupus, and *we would like to setup* a public fund," after discussing business need with Mallinckrodt COO) (emphasis added); Compl. ¶ 111 (Reimbursement Manager reporting back to the COO after discussion with CDF that "*We can have a fund established* next week if you'd like") (emphasis added); Compl. ¶ 121 (Reimbursement Manager contacting CDF "to discuss setting up a public fund for RA" and "[w]e'd like to work with you on what to call this").

When CDF did not respond fast enough to its requests, Mallinckrodt pressured CDF. *See, e.g.*, Compl. ¶ 112 (Mallinckrodt to CDF about lupus fund: "[c]an you help me out with this?"); Compl. ¶ 125 (Mallinckrodt to CDF about RA fund: "Sorry to be a pest but I'm at a meeting with the COO and the Commercial VP and they are constantly asking me if I've heard any information from you guys"). As a result of this pressure, CDF instructed its personnel to hold open Acthar referrals if they could be paid by a fund Mallinckrodt wanted to open shortly. Compl. ¶ 122. Unsurprisingly, and contrary to its Motion, at the time of the conduct, Mallinckrodt personnel plainly viewed the funds as their own. *See, e.g.*, Compl. ¶ 98, 126.

Symptom funds. The Complaint also specifically alleges that Mallinckrodt persistently sought and received artificially narrowly defined funds, designed by Mallinckrodt to favor

Acthar exclusively. Mallinckrodt accomplished this by defining funds around a disease's symptoms or their severity, rather than a disease itself. Compl. ¶ 182; *see also id.* ¶¶ 47-48, 52-53, 55-56. Mallinckrodt was explicit about this motivation. *See, e.g., id.* ¶ 88 (seeking new fund specific to MS "exacerbations" "to prevent chronic MS needs from tapping the funds"); ¶ 112 (seeking Lupus "exacerbation" label "so we don't open ourselves up to other drugs being used for maintenance"). Further confirming the company's intent to favor Acthar, the Complaint alleges that Mallinckrodt did not intend to place any limitation on the Acthar patients it sent to the "exacerbation" funds, and indeed sent continuous, costly "pulse-maintenance" Acthar refills there rather than just "exacerbation" prescriptions. Compl. ¶¶ 101-103 (allegations of MS "pulse maintenance" referrals); *see id.* ¶¶ 112 (acknowledging that "if we established the fund for [Lupus] exacerbations, Acthar patients that may be prescribed Acthar for maintenance could still get coverage."); *id.* ¶ 118-120 (allegations of Lupus continuous long-term referrals); *id.* ¶¶ 126-127 (same for RA).

Data. The Complaint alleges that Mallinckrodt also requested, received, and reviewed data to track its payment of copay subsidies. Compl. ¶¶ 147-155; 183. This enabled Mallinckrodt to ensure its payments to CDF were used for Acthar copays, and to keep paying the amount necessary to subsidize Acthar copays without interruption. *Id.* ¶¶ 147-155. This also enabled Mallinckrodt to incorporate copay subsidies into its commercial and marketing operations.

Conduit. Mallinckrodt used CDF as a conduit to pay Acthar copays. The Complaint alleges that Mallinckrodt flooded the "exacerbation" funds with referrals from its marketing apparatus, knowing virtually all would receive Mallinckrodt-funded subsidies, and allowing the company to market Acthar as "free" despite its exorbitant price. *See* Compl. ¶¶ 129-133; 137-

145. At the same time, Mallinckrodt excluded Medicare patients from its charitable free drug program in favor of sending them to CDF to induce Medicare-reimbursed Acthar sales. *See e.g., id.* ¶¶ 134-136. Meanwhile, Mallinckrodt paid exactly what CDF said was necessary to fund the copays of Acthar patients in the queue. *Id.* ¶¶ 147-155. Mallinckrodt's scheme was profitable; the company believed these copay subsidies were key to its Acthar sales efforts; and, with its conduit operational, the company kept increasing Acthar's price. *Id.* ¶¶ 156-161.

B. THE COMPLAINT PLAUSIBLY ALLEGES SCIENTER

Mallinckrodt also asks the Court to determine that it lacked the requisite scienter under the AKS and FCA, adopting a post-hoc rationale that Mallinckrodt's actions were "objectively reasonable," regardless of Mallinckrodt's intent *at the time*. Def's Mot. 19-23. But courts have rejected this framework, holding that a defendant's contemporaneous intent is what matters, even in the face of statutory ambiguity which is absent here. *See, e.g., United States ex rel. Phalp v. Lincare Holdings Inc.*, 857 F.3d 1148, 1155 (11th Cir. 2017) ("[S]cienter is not determined by the ambiguity of a regulation, and can exist even if a defendant's interpretation is reasonable."); *United States ex rel. Minnesota Ass'n of Nurse Anesthetists v. Allina Health Sys. Corp.*, 276 F.3d 1032, 1053-54 (8th Cir. 2002) ("If the Association shows the defendants certified compliance with the regulation knowing ... that their actions did not satisfy the requirements of the regulation as the [government] interpreted it, any possible ambiguity of the regulation is water under the bridge."); *United States ex rel. Bahnsen v. Bos. Sci. Neuromodulation Corp.*, No. 11-1210, 2017 WL 6403864, *9 (D.N.J. Dec. 15, 2017) ("[T]he timing of a defendant's reasonable interpretation is critical . . . a claimant cannot avoid liability by manufacturing an after-the-fact reasonable interpretation of an ambiguous provision."); *United States ex rel. Streck v. Bristol-Myers Squibb Co.*, No. 13-7547, 2018 WL 6300578, *12 (E.D. Pa. Nov. 29, 2018) ("a court

should not resolve an FCA claim at the motion to dismiss stage where the plaintiff plausibly alleges that the defendant proceeded with its interpretation in the face of contrary guidance”) *mot. for reconsideration denied* at 370 F. Supp. 3d 491, 496 (E.D. Pa. 2019) (whether guidance warned defendant away “presents a question of fact”).

The Complaint alleges Mallinckrodt’s contemporaneous knowing and willful scienter. Mallinckrodt cannot now ask the Court to disregard that allegation and dismiss this case at the pleading stage. *Phillips*, 515 F.3d at 233; *Connelly*, 809 F.3d at 786; *McDermott*, 649 F. App’x at 269 n. 3.

In addition, Mallinckrodt’s request that the Court adopt facts contrary to the Complaint from HHS-OIG materials is improper. *See United States ex rel. Spay v. CVC Caremark Corp.*, 913 F. Supp. 2d 125 at 156 (E.D. Pa. 2012) (“To the extent, however, that Defendant asks for judicial notice of facts gleaned from” public documents attached to Defendant’s motion to dismiss “the Court declines to do so.”). Indeed, such factual disputes are often insufficient to support post-discovery summary judgment, let alone a motion to dismiss, as determinations of intent under the AKS and the FCA are traditionally within the purview of the factfinder.⁸

Nevertheless, Mallinckrodt cites *Safeco Insurance Co. of America v. Burr*, 551 U.S. 47 (2007), to argue that the Complaint should be dismissed on the pleadings, regardless of Mallinckrodt’s intent at the time. Although not cited by Mallinckrodt, the Supreme Court’s

⁸ *See, e.g., United States ex rel. Cantekin v. Univ. of Pittsburgh*, 192 F.3d 402, 411 (3d Cir. 1999) (“In applying [the FCA’s knowledge] standards to the record before us, we must heed the basic rule that a defendant’s state of mind typically should not be decided on summary judgment.”); *United States ex rel. Bartlett v. Ashcroft*, 39 F. Supp. 3d 656, 679 (W.D. Penn. 2014) (“determining whether a business arrangement violates the Anti-Kickback Statute is largely a question of intent, resolution of which is the province of the trier of fact.”); *Riehl v. Travelers Ins. Co.*, 772 F.2d 19, 24 (3d Cir. 1985) (“[I]ssues of knowledge and intent are particularly inappropriate for resolution by summary judgment[.]”).

recent decision in *Halo Electronics, Inc. v. Pulse Electronics, Inc.*, 136 S. Ct. 1923 (2016), made clear that *Safeco* does support this argument. *Id.* at 1933 (“Nothing in *Safeco* suggests that we should look to facts that the defendant neither knew nor had reason to know at the time he acted.”). Instead, the Court reaffirmed that “culpability is generally measured against the knowledge of the actor at the time of the challenged conduct” rather than “the strength of his attorney’s ingenuity” in justifying conduct after the fact. *Id.*

Defendant also misreads *United States ex rel. Streck v. Allergan, Inc.*, 746 F. App’x. 101 (3d. Cir. 2018), as adopting its rejected reading of *Safeco*. In *Streck*, the Third Circuit concluded that defendants did not knowingly violate the FCA by excluding price-appreciation credits in calculating a drug’s average manufacturer price because the pricing statute was ambiguous, and there was no evidence that the defendants were aware at the time that their reading of the statute was erroneous. 746 F. App’x. at 108-09. Thus, *Streck* does not support Mallinckrodt’s argument that a defendant can avoid scienter as a matter of law merely by claiming that its conduct conformed to an objectively reasonable interpretation of the law, regardless of contemporaneous intent.

In any event, Mallinckrodt’s argument fails even applying the *Safeco* analysis, because: 1) the AKS unambiguously prohibits knowingly and willfully paying Medicare copays to induce Medicare purchases; 2) even if there were ambiguity, Mallinckrodt cannot establish a reasonable contemporaneous interpretation; and 3) even if it could, Mallinckrodt was warned away from its conduct. *See Streck*, 746 F. Appx. at 106 (citing *Safeco* 551 U.S. at 68-70)).

First, the Anti-Kickback Statute’s prohibition on knowingly and willfully paying Medicare copays to induce Medicare sales is not ambiguous. It explicitly prohibits “knowingly and willfully offer[ing] or pay[ing] any remuneration (including any kickback, bribe, or rebate)

directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person . . . to purchase or arrange for or recommend purchasing any good . . . or item for which payment may be made in whole or in part under a Federal health care program.” 42 U.S.C. 1320a-7b(b)(2)(B). There is no ambiguity concerning whether money for copay subsidies is remuneration or whether Medicare-reimbursed Acthar prescriptions are “good[s]” or “item[s]” within the statute’s purview. Thus, there is no ambiguity that paying copay subsidies knowingly and willfully to induce Medicare to reimburse an Acthar prescription violates the statute. *See, e.g., United States v. Williams*, 218 F. Supp. 3d. 730, 740 (N.D. Ill. 2016) (AKS parallel provision prohibiting paying remuneration to induce referrals “does provide a person of ordinary intelligence with a reasonable opportunity to know what is prohibited.”); *United States v. Mathur*, No. 2:11-CR-00312-MMD, 2012 WL 4742833, at *13 (D. Nev. Sept. 13, 2012) (The AKS “is not ambiguous about whether bribes, kickbacks, or rebates may be offered or paid to induce referrals of Medicare business.”) *report and recommendation adopted*, No. 2:11-CR-00312-MMD, 2012 WL 4711960 (D. Nev. Oct. 3, 2012).

Tellingly, Mallinckrodt does not cite a single case holding otherwise or dismissing AKS allegations on these grounds. Instead, Mallinckrodt argues that the asserted differences between the 2014 SAB and the 2005 SAB are grounds to do so, relying on *United States ex rel. Pritsker v. Sodexo, Inc.*, No. 03-6003, 2009 WL 579380 (E.D. Pa. Mar. 6, 2009), *aff’d*, 364 F. App’x 787 (3d Cir. 2010). There, the Court dismissed relator’s FCA allegations premised on an interpretation of a regulation that, during the time period in question, was contradicted by the position of the federal agency administering the grant program at issue. Moreover the agency had taken the opposite position at a prior time. *Id.* at *16. Neither is remotely analogous to this

situation, where the AKS has always prohibited conduct like that at issue in this case and the agency guidance has been consistent in describing the risks of arrangements like Mallinckrodt's.

Second, Mallinckrodt cannot establish that it had a contemporaneous, reasonable alternative interpretation of the AKS, as it would need to. *See supra*, 18-19. Indeed, the Complaint alleges the opposite, *see, supra* 6-11, and appending publicly available materials does not give Mallinckrodt an end run around the Complaint's detailed allegations that it acted knowingly and willfully. *See Phillips*, 515 F.3d at 233; *Connelly*, 809 F.3d at 786; *McDermott*, 649 F. App'x at 269 n. 3; *Spay*, 913 F. Supp. 2d at 156. In any event, nothing in the materials attached to the Motion shows that Mallinckrodt's scheme could have reasonably been interpreted to be consistent with these materials or the AKS. *See, supra* 16-18.

Third, the materials cited by Mallinckrodt demonstrate that Mallinckrodt was warned away from its conduct, and the Complaint specifically alleges as much. *Id.*; *see, supra* 7-8. Mallinckrodt's assertion that it was *not* warned away is, again, a factual dispute, contrary to the Complaint's allegations, and should not be inferred on a motion to dismiss. *Bristol-Myers Squibb Co.*, 2018 WL 6300578 at *12 (E.D. Pa. Nov. 29, 2018); *see Spay*, 913 F. Supp. 2d at 156; *Cantekin*, 192 F.3d at 411; *Bartlett*, 39 F. Supp. 3d at 679; *Riehl*, 772 F.2d at 24. Mallinckrodt's motion should be denied.

III. MALLINCKRODT'S MOTION TO STRIKE SHOULD BE DENIED

Mallinckrodt also requests that the Court strike Paragraph 199 of the Complaint and its accompanying footnote under Federal Rule 12(f).⁹ Def's Mot. at 23-24. That Paragraph and

⁹ Federal Rule 12(f) allows courts to strike "redundant, immaterial, impertinent, or scandalous matters" and "striking a pleading is a drastic remedy to be resorted to only when required for the purposes of justice and should be used sparingly." *DeLa Cruz v. Piccari Press*, 521 F. Supp. 2d 424, 428 (E.D. Pa. 2007) (citation omitted) (denying motion to strike); *Giuliani v. Polysciences, Inc.*, 275 F. Supp. 3d 564, 572 (E.D. Pa. 2017).

footnote state that the United States regularly enforces the AKS, pursues FCA liability based on underlying violations of the AKS, and has recovered over \$840 million in FCA actions against at least eight drug companies for knowingly and willfully paying Medicare copays by using foundations as conduits. Compl. ¶ 199.¹⁰ In arguing that these publicly available materials should be stricken from the Complaint, Mallinckrodt misconstrues their content, misstates the law, and misapprehends the purpose of that paragraph.

First, despite Mallinckrodt's suggestion otherwise, these actions indeed involve conduct dating back to 2010, as alleged here. Second, Mallinckrodt suggests that the government's pursuit of civil FCA actions in these matters (as opposed to criminal AKS violations) somehow supports the arguments in its own motion. Def's Mot. at 24. Tellingly, Mallinckrodt does not cite a case for this proposition, because the government is free to pursue whatever enforcement action it wishes and courts routinely hold that the lack of a criminal prosecution is not relevant to, or admissible in, a civil case. *See, e.g., Johnson v. Elk Lake Sch. Dist.*, 283 F.3d 138, 147 (3d Cir. 2002) ("evidence of non-arrest, like evidence of nonprosecution or acquittal of a crime, is generally inadmissible in a civil trial concerning the same incident") (citation omitted). Third, Mallinckrodt's implication that this paragraph is offered for any purpose other than further context in which to read Congress's command that AKS-tainted claims are materially false is inaccurate. Def's Mot. at 24. As Mallinckrodt recognizes, "[c]laims for payment made pursuant to illegal kickbacks are false under the False Claims Act." Def's Mot. at 13 (quoting *Greenfield* 880 F.3d at 95). Paragraph 199 merely underscores that violations of the AKS are

¹⁰ Paragraph 199 includes a footnote providing citations to five publicly available Department of Justice press releases announcing the eight separate enforcement actions. Mallinckrodt attaches four of these press releases to its motion. Def's. Ex. S.

material as a matter of law. *See, e.g., Guilfoile v. Shields*, 913 F.3d 178, 190-91 (1st Cir. 2019) (Section 1320a-7b(g) “essentially codifies the long-standing view that AKS violations are ‘material’ in the FCA context.”); *United States ex rel. Lutz v. Berkeley Heartlab, Inc.*, No. 14-cv-230, 2017 WL 6015574 at *2 (D.S.C. Dec 4, 2017) (stating that “the only reasonable inference” from 42 U.S.C. § 1320a-7b(g) “is that AKS violations are per se material”). Paragraph 199 appears in a section outlining this legal framework and is offered in that context, which is wholly appropriate. Accordingly, Mallinckrodt fails in its heavy burden to “demonstrate that the allegations have no possible relation to the controversy and may cause prejudice to one of the parties, or that the allegations confuse the issues” and the court should deny its request. *DeLa Cruz*, 521 F. Supp. 2d at 428 (citation omitted).

CONCLUSION

For the foregoing reasons, the United States respectfully requests that Mallinckrodt’s Motion be denied in its entirety.

Respectfully submitted,

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CERTIFICATE OF SERVICE

It is hereby certified that a copy of the foregoing United States' Response in Opposition to Defendant's Motion to Dismiss was sent via ECF this 24th day of September, 2019, to the following:

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